REMARKS/ARGUMENTS

Responsive to the Office Action dated February 22, 2007, Applicants respectfully request consideration of the following remarks and reconsideration of the application. Claims 28 and 29 have previously been canceled. Claims 1-27 are pending and under consideration. Claims 4, 5, 23, and 25-26 have been cancelled. Claims 1-3, 6-7, 9-10, 13-15, 18-19, 21-22, 24 and 27 have been amended. Applicants submit that no new matter has been added by way of these amendments. Each of these claims is believed to be in condition for allowance and such favorable action is requested.

§112 Rejections

A.) Rejections Based on Enablement Requirement

Claims 1-27 have been rejected under 35 U.S.C. §112 for failing to comply with the enablement requirement. In particular, claims 1-27 were rejected as failing to comply with the enablement requirement as the Office contends that the claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to make and/or use the invention. Applicants have amended independent claims 1 and 24 t be directed to obtaining a fecal sample from a person other than a breast-fed infant. As such, Applicants request withdrawal of the §112, first paragraph, rejection of claims 1-27.

B.) Rejections Based on 112, Second Paragraph

Claims 1-27 have been rejected for not using positive steps delimiting how the use of lactoferrin is actually practiced. The claims have been amended to recite positive steps of determining whether a fecal sample has an elevated level of lactoferrin. As such, Applicants request withdrawal of this §112 rejection.

Claims 17-19 and 20-22 have been rejected for the use of the term "if so" making the steps of claims 17-19 and 20-22 optional. Applicants have amended independent claim 1 to

positively recite the claimed step. As such, amended claim 1 does not contain any optional steps. As such, Applicants request withdrawal of these rejections.

Claims 13 and 14 have been rejected as being indefinite for failing to particularly point out and distinctly claim the subject matter Applicants regard as the invention. Applicants have amended claims 13 and 14 to include how the antibodies create a readable sample. As such, Applicants request withdrawal of these rejections.

Claims 13-14, 17-18, and 21-23 have been rejected for being incomplete for omitting essential elements. Applicants have amended the claims to include these elements. As such, Applicants request withdrawal of these rejections.

Claims 13-14, 18-19, and 21-23 have been rejected for being incomplete for omitting essential elements. Applicants have amended the claims to include these elements. As such, Applicants request withdrawal of these rejections.

Claims 15-16 have been rejected because "purified lactoferrin" lacked proper antecedent basis. Applicants have amended the claim and submit that claim 15 is the first time "purified lactoferrin" is used in the claim set to generate a standard curve. As such, Applicants request withdrawal of these rejections.

§102 Rejections

A.) Applicable Authority

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdeggal Brothers v. Union Oil Co. of California*, 814 F.2d 628, 631 2 USPQ 2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the . . . claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 2 USPQ 2d 1913, 1920 (Fed. Cir. 1989). *See also*, MPEP §2131.

B.) Anticipation Rejections Based on the Guerrant Reference (US Pat. 5,124,252)

Claims 1, 8-12, 13, 15, and 24-25 have been rejected as being anticipated by Guerrant et al, (US Pat. 5,124,252) (hereinafter the "Guerrant reference.") As the Guerrant reference fails to describe, either expressly or inherently, each and every element as set forth in the rejected claim, Applicants respectfully traverse these rejections.

Claim 1, as amended, is directed to a method for testing a fecal sample from a person for diagnosis. The method comprises obtaining a fecal sample from a person and determining whether the sample contains an elevated level of lactoferrin. The method further comprises determining whether the sample contains an elevated level of anti-*Saccharomyces cerevisiae* antibodies (ASCA) and an elevated level of anti-neutrophil cytoplasmic antibodies (ANCA) if the sample contains an elevated level of lactoferrin. A diagnosis of Crohn's disease may be substantially concluded if the sample contains an elevated level of anti-*Saccharomyces cerevisiae* antibodies and a diagnosis of ulcerative colitis may be substantially concluded if the sample contains an elevated level of anti-neutrophil cytoplasmic antibodies.

Claim 24, as amended, recites a method for distinguishing inflammatory bowel disease from irritable bowel syndrome and for differentiating ulcerative colitis from Crohn's disease. The method comprises obtaining a fecal sample from a person and determining whether the sample contains an elevated level of lactoferrin. The method further comprises determining if the sample contains an elevated level of anti-*Saccharomyces cerevisiae* antibodies (ASCA) and an elevated level of anti-neutrophil cytoplasmic antibodies (ANCA) if the sample contains an elevated level of lactoferrin. The method further includes diagnosing the person with irritable bowel syndrome if the sample does not contain an elevated level of lactoferrin and diagnosing the person with inflammatory bowel disease if the sample contains an elevated level of lactoferrin. A person is diagnosed with Crohn's disease if the sample contains an elevated level

of anti-*Saccharomyces cerevisiae* antibodies and a person is diagnosed with ulcerative colitis if the sample contains an elevated level of anti-neutrophil cytoplasmic antibodies.

Applicants have amended claims 1 and 24 such that the steps of determining whether a fecal sample contains elevated levels of ASCA and ANCA are not optional. As such, the Guerrant reference discloses only the method of obtaining a fecal sample from a person and determining whether lactoferrin is present in the sample; it does not discuss determining whether a fecal sample contains an elevated level of ASCA and ANCA. As such, Guerrant reference does not anticipate the claimed invention, and Applicants request withdrawal of the 103(a) rejection of claims 1 and 24. As claims 8-12, 13, and 15, as amended, depend directly or indirectly from claim 1, Applicants request withdrawal of the rejection of these claims as well.

C.) Anticipation Rejection Based on the Fine Reference (Fine et al., *American Journal of Gastroenterology*, Vol. 93, No. 8, pp 1300-1305, 1998.)

Claims 1-3, 11-12, 24-26, and 27 have been rejected as being anticipated by Fine et al, (Fine et al., American Journal of Gastroenterology, Vol. 93, No. 8, pp 1300-1305, 1998 (hereinafter the "Fine reference"). Because the Fine reference fails to describe, either expressly or inherently, each and every element as set forth in the rejected claim, Applicants respectfully traverse this rejection.

Applicants have amended claims 1 and 24 such that the steps of determining whether a fecal sample contains elevated levels of ASCA and ANCA are not optional. The Fine reference discloses only the method of obtaining a fecal sample from a person; determining whether lactoferrin is present in the sample. As such, the Fine reference does not anticipate the claimed invention, and Applicants request withdrawal of the 103(a) rejection of claims 1 and 24. Because claims 2-3, 11, and 12, as amended, depend directly on claim 1, and claim 27, as

amended, depends directly on claim 24, as amended, Applicants request withdrawal of the rejection of these claims as well.

D.) Anticipation Rejection Based on the Martins Reference (Martins et al., *Clinical and Diagnostic Laboratory Immunology*, Vol. 2, No. 6, pp. 763-765, 1995).

Claims 24 and 26 have been rejected as being anticipated by Martins et al., *Clinical and Diagnostic Laboratory* Immunology, Vol. 2, No. 6, pp. 763-765, 1995 (hereinafter the "Martins reference"). Applicants submit that Martins does not teach or suggest all of the claimed features of independent claim 24. In particular, amended claim 24 is directed to obtaining a fecal sample from a patient and determining whether it contains an elevated level of lactoferrin. Martins, on the other hand, discusses a method of obtaining a whole blood, saliva, sputum, or gingival swab from a patient and determining whether lactoferrin is present in the sample. Martins fails to teach or suggest testing a fecal sample of a person for elevated lactoferrin. As such, Applicants request withdrawal of the rejection of claims 24 and 26.

§ 103(a) Rejections

A.) Applicable Authority

To establish a prima facie case of obviousness, three criteria must be met:

1) there must be some suggestion or motivation to modify the reference or to combine reference teachings;

2) there must be a reasonable expectation of success; and

3) the prior-art references must teach or suggest all the claim limitations.

Moreover, the teaching or suggestion, and the reasonable expectation of success must be found in the prior art and not be based on Applicants' disclosure. *See* MPEP § 706.02(j), § 2142, and § 2143.

B.) Obviousness Rejection Based on the Nielson Reference (Nielson et al., *The American Journal of Gastroenterology*, Vol. 95, No. 2, 359-367, 2000) in View of the Targan Reference (*Journal of Immunology*, 1995, Vol. 155, Issue 6, 3262-3267, 1995) and the Fine (2) Reference (PG – Pub 2001/0036639A1, filing date March 2, 2001).

Claims 1-10 and 24-26 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Nielson et al. (*The American Journal of Gastroenterology*, Vol. 95, No. 2, 359-367, 2000) (hereinafter the "Nielson reference") in view of Targan et al. (*Journal of Immunology*, 1995, Vol. 155, Issue 6, 3262-3267, 1995) (hereinafter the "Targan reference") and Fine (PG – Pub 2001/0036639A1, filing date March 2, 2001) (hereinafter "the Fine (2) reference"). Applicants submit that none of the cited references, singularly or in combination, teach or suggest all of the claimed limitations of independent claims 1 and 24.

Claim 1, as amended, is directed to a method for testing a fecal sample from a person for diagnosis. The method comprises obtaining a fecal sample from a person and determining whether the sample contains an elevated level of lactoferrin. The method further comprises determining whether the sample contains an elevated level of anti-*Saccharomyces cerevisiae* antibodies (ASCA) and an elevated level of anti-neutrophil cytoplasmic antibodies (ANCA) if the sample contains an elevated level of lactoferrin. A diagnosis of Crohn's disease may be substantially concluded if the sample contains an elevated level of anti-*Saccharomyces cerevisiae* antibodies and a diagnosis of ulcerative colitis may be substantially concluded if the sample contains an elevated level of anti-neutrophil cytoplasmic antibodies.

Applicants submit that Nielsen in view of Targan in view of Fine neither teaches nor suggests determining whether a fecal sample contains an elevated of ANCA in response to the fecal sample containing an elevated level of lactoferrin. Nielsen discloses testing for ANCA in serum. (See Nielsen, Page 361). Nielsen does not teach testing a fecal sample for an elevated

level of ANCA. Furthermore, there is no teaching or suggestion in Nielsen that ANCA can cross through the intestinal wall from the serum and be contained in feces.

Targan does not cure this deficiency. Like Nielsen, Targan determines the presence of ANCA is determined in a serum sample. (See Targan, Page 3262). Targan does not teach testing a fecal sample for an elevated level of ANCA. Furthermore, there is no teaching or suggestion in Targan that ANCA can cross through the intestinal wall from the serum and be contained in feces.

Likewise, Fine does not teach or suggest determining whether a fecal sample contains an elevated level of ANCA in response to the fecal sample containing an elevated level of lactoferrin. Rather, Fine teaches a method for diagnosing food sensitivities Fine does not discuss determining whether a fecal sample contains an elevated level of ANCA. In addition, Fine does not teach or suggest a fecal sample contains an elevated level of anti-*saccharomyces cerevisiae* antibodies is an indicator of Crohn's disease. Rather, Fine teaches a method for diagnosing food sensitivities. Crohn's disease is not a food sensitivity to *Saccharomyces cerevesiae*. Fine does not teach or suggest that ASCA can be used to diagnose Crohn's disease.

Claim 24, as amended, recites a method for distinguishing inflammatory bowel disease (IBD) from irritable bowel syndrome (IBS) and for differentiating ulcerative colitis from Crohn's disease. The method comprises obtaining a fecal sample from a person presenting with symptoms common to inflammatory bowel disease and irritable bowel syndrome and determining whether the sample contains an elevated level of lactoferrin. The method further comprises diagnosing the person with irritable bowel syndrome if the fecal sample does not contain an elevated level of lactoferrin and diagnosing the person with inflammatory bowel disease if the fecal sample contains an elevated level of lactoferrin. It is determined whether the person has an elevated level of anti-*Saccharomyces cerevisiae* antibodies (ASCA) and an

elevated level of anti-neutrophil cytoplasmic antibodies (ANCA) if the fecal sample contains an elevated level of lactoferrin and the person has been diagnosed with inflammatory bowel disease to differentiate Crohn's disease from ulcerative colitis. The person is diagnosed with Crohn's disease if the sample contains an elevated level of anti-*Saccharomyces cerevisiae* antibodies and is diagnosed with ulcerative colitis if the sample contains an elevated level of anti-neutrophil cytoplasmic antibodies.

The method of claim 24 includes distinguishing between IBD and IBS. When a patient presents with symptoms common to IBD and IBS, it is difficult to distinguish between the two conditions. Claim 24 relates to diagnosing IBS when a patient presents with symptoms common to IBD and IBS if the level of fecal lactoferrin is not elevated for the patient. The prior art does not teach this. Specifically, the Nielson, Targan and Fine do not teach measuring the level of lactoferrin in patients with IBS. It was unknown whether patients with IBS had elevated levels of lactoferrin. More specifically, while Nielson teaches that fecal lactoferrin may be utilized as a marker for disease activity in IBD, the Nielson is silent as to whether patients with IBS have elevated levels of lactoferrin.

Targan and Fine do not cure this deficiency. Targan and Fine also fail to teach or suggest diagnosing IBS when a person presents with symptoms common to IBD and IBS if the level of fecal lactoferrin is not elevated for the patient. Targan determines the presence of ANCA in a serum sample and does not discuss determining the level of lactoferrin in a fecal sample. (See Targan, Page 3262). Fine teaches a method for diagnosing food sensitivities and does not discuss determining the level of lactoferrin in a fecal sample.

Applicants submit that Nielsen in view of Targan in view of Fine neither teaches nor suggests all the claim limitations of independent claims 1 and 24. As such, the present application is believed to be in condition for allowance, and Applicants request that a timely

notice of allowance be issued for this case. Should any unresolved issues remain in the case, please feel free to contact the undersigned at the phone number listed below.

The fee for a three-month extension of time is submitted herewith. It is believed that no additional fee is due in conjunction with the present communication. However, if this belief is in error, the Commissioner is hereby authorized to charge any amount required to Deposit Account No. 19-2112, referencing attorney docket number TLAB.100292.

Dated: August 22, 2007

Respectfully submitted,

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